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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,668	08/25/2006	Andrew Childs	1045-006	3787

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EXAMINER	
WANG, CHUN CHENG	
ART UNIT	**PAPER NUMBER**
1796	
MAIL DATE	**DELIVERY MODE**
09/15/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,668	CHILDS ET AL.	
	Examiner	Art Unit	
	Chun-Cheng Wang	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,8,11 and 12* is/are rejected.

7)☒ Claim(s) *7,9 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/08/2010 has been entered.

2. Claim 1 has been cancelled. Claims 2-13 are pending.

3. The text of those sections of Title 35, U.S. Code not included in this section can be found in a prior Office Action.

Claim Rejections - 35 USC § 102

4. Claims 2-6, 8, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Fukuda (US 4254105) (referenced as Fukuda hereinafter) as evidenced by Sebba (US 4486333) (column 1, lines 31-47) and Menger et al., (Microscopic Observation of a Polyaphron Transforming into a Microemulsion, J. Am. Chem. Soc. 1991, 113, 5119-5120) (last three lines of left column, page 5119).

Claim 12: Fukuda discloses a high internal phase ratio (78 wt% internal phase and about 22 wt% external phase, EXAMPLE 10: Nutrient cream) multiple emulsion (read on polyaphron). Fukuda discloses a multiple emulsion prepared by dissolving an oil-soluble emulsifier into oil component; adding water to the resulting solution to form a W/O emulsion; and finally adding this W/O emulsion to an aqueous solution which is prepared by dissolving a water-soluble emulsifier into water; and emulsifying the W/O emulsion as a dispersed phase (e.g. internal phase having two liquid phase at room temperature: water and oil) into the aqueous solution

(column 2, lines 62-67 and column 3, lines 1-12). Fukuda also discloses at least one saccharide is dissolved in the water phase of W/O emulsion that is the dispersed phase of the W/O/W emulsion. The saccharide addition improves the properties of the W/O/W emulsion by the fact that the formation of a complex between the saccharide and certain functional group, e.g., sorbitan portion, of the surface active agent through hydrogen bond increases mechanical strength of the inter-facial film of the W/O emulsion, allowing the W/O emulsion, that is dispersed phase of the W/O/W emulsion, to exist sufficiently stable in the dispersion medium (column 2, lines 30-52).). Fukuda also further surfactant sucrose fatty acid ester and distilled water are also used to form the nutrient cream (column 14, Example 10). The sucrose group of the sucrose fatty acid ester and water form strong hydrogen-bond thus forms an aqueous inter-facial film between the water and oil to stabilize the emulsion.

Claims 2-5: Fukuda discloses the multiple emulsion having a dispersing form of water-phase/oil-phase/water-phase (Abstract, line 1) with water as external phase and water-in–oil emulsion as internal phase with liquid phases comprising water (aqueous phase) and oil (non-aqueous phase).

Claim 6: The multiple emulsion comprises a dispersing form of water-phase/oil-phase/water-phase (Abstract, line 1) where the internal phase is a water-in–oil emulsion (see W/O emulsion of EXAMPLE 10).

Claim 8: Fukuda discloses as an oil component, which is used for the formation of W/O emulsion, one or more of appropriate fats, oils and waxes (read on solid in the internal phase) may be selectively used for various purposes (column 4, lines 9-32).

Claim 11: Fukuda discloses to prepare W/O emulsion, i.e. prepare the internal phase, first. To a surfactant containing aqueous solution (e.g. external phase), the W/O emulsion was added under agitation, the W/O/W multiple emulsion was formed (e.g. polyaphron dispersion) (column 14, Example 10).

Claim Rejections - 35 USC § 103

5. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fukuda (US 4254105) in view of Barnett et al. (US 4999198) (referenced as Barnett hereinafter).

The disclosure of Fukuda is adequately set forth in paragraph 4 and is incorporated herein by reference.

Fukuda is silent on component of the external phase is capable of reacting a component of the internal phase.

Fukuda is working on preparing the w/o/w emulsion that may be used as the fundamental form for various products requiring emulsified dispersion system such as cosmetics and drugs (column 1, lines 11-19). Fukuda is working on preparing the w/o/w emulsion with high stability (column 3, lines 58-60).

Barnett discloses forming a polyaphron having a continuous phase and a disperse phase. A drug is carried in the dispersed phase (Abstract). Since polyaphrons, like other dispersed systems, are subject to interfacial instabilities, it is felt that polymerization of the polyaphrons may significantly increase the life of the system (column 3, lines 19-30). The drug release rate can be controlled by polymerization of either phase, such as by the addition of monomers to the oil and water phase to obtain polymerization at the interface for release control. Further, the

polymerization concept is applicable in either phase in order to establish a matrix for precise control of delivery rates (column 3, lines 53-64).

In light of the benefit, it would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains to add monomers in external phase and internal phase to perform interfacial polymerization to significantly increase the life by precise control of delivery rates of the system in the same field of endeavor and have reasonable expectation to be successful.

Allowable Subject Matter

6. Claims 7, 9 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance:

The present claims are allowed over the closest references: Fukuda (US 4254105) (referenced as Fukuda hereinafter).

Fukuda discloses a high internal phase ratio (78 wt% internal phase and about 22 wt% external phase, EXAMPLE 10: Nutrient cream) multiple emulsion (read on polyaphron). However, Fukuda does not teach or fairly suggest the claimed polyaphron dispersion wherein the internal phase comprises polyaphrons, wherein the internal phase comprises at least 60% of an aqueous phase, and wherein the second phase is gaseous and the internal phase additionally comprises a solid phase.

There is no prior art of record, alone or in combination teach or fairly suggest the claimed polyaphron dispersion.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Response to Arguments

7. Applicant's arguments filed 07/08/2010 have been fully considered but they are not persuasive.

8. Applicants argued: Example 11 is an emulsion and not a polyaphron dispersion.

Response: Examiner would like to point out that the rejections in the previous Office actions are based on Fukuda Example 10. The Fukuda Example 11 is irrelevant to this Office action.

9. Applicant alleged: "Examiner has failed to point to the teaching in Fukuda of a polyaphron dispersion wherein when the internal phase comprises at least two liquid phases, each of the liquid phases is a liquid at room temperature".

Response: Prior art Sebba (US 4486333) teaches: A water-lamella biliquid foams … in which the discontinuous oil phase is separated from the continuous aqueous phase by a single interface. In the composition under consideration, the globules of non-polar liquid are encapsulated in a double surfaced film of a hydrogen bonded liquid which is immiscible with the non-polar liquid and contains a soluble surfactant. Such units which have been called by the Applicant "aphrons" are dispersed in a continuous phase of the hydrogen bonded liquid. When the concentration of the aphrons gets large enough (it is noted: high internal phase ratio) for them

to interfere with one another, the dispersion medium becomes compressed into a lamella so that a **biliquid foam** develops. Such a biliquid foam is in fact an aggregate of aphrons and is thus called a **polyaphron** (column 1, lines 31-47). Sebba fairly suggests the polyaphron dispersion has high internal phase ratio. And Menger et al., (Microscopic Observation of a Polyaphron Transforming into a Microemulsion, J. Am. Chem. Soc. 1991, 113, 5119-5120) clearly state "A **polyaphron** (also called a **high internal phase ratio emulsion**) has been likened to a gas-in-liquid foam in which the gas has been replaced by a second liquid" (last three lines of left column, page 5119). Fukuda Example 10 teaches a high internal phase ratio w/o/w emulsion comprising sucrose fatty acid ester surfactant (sucrose hydrophilic group and fatty acid lipophilic group), 78 wt% of a w/o emulsion as internal phase and 20 wt% of water as external phase that meet the high internal phase ratio weight % limitation of claim 12 and the definition of polyaphrons. The Fukuda Example 10 also teaches use of cosbiol, olive oil (second phase) and water (first phase), which are liquids at room temperature, to form the w/o emulsion (internal phase). Claim 12 does not exclude solid phase in the internal phase. The continuous water phase has low phase ratio, the continuous would be compressed into a lamella such that biliquid foam (nutrient cream) developed. Applicant did not show any data otherwise.

10. Response to applicant's argument about rejection of claim 10 under 35 U.S.C. 103(a) as being unpatentable over Fukuda (US 4254105) in view of Barnett et al. (US 4999198):

First, The Fukuda Example 10 emulsion is a high internal phase ratio emulsion and meets each and all the limitations of claim 12.

Second, Barnett overcomes the deficiency by disclosing the drug release rate (of the polyaphron drug delivery system) can be controlled by polymerization of either phase, such as

by the addition of monomers to the oil and water phase to obtain polymerization at the interface for release control. Further, the polymerization concept is applicable in either phase in order to establish a matrix for precise control of delivery rates (column 3, lines 53-64) thus prolong (stabilize) the life of the system.

Third, both Fukuda and Barnett are working on preparing the emulsion with high stability. Fukuda is working on a system carry drug and Barnett is working on a drug delivery system. Control of drug delivery rate, not too high or too low dosage, prolong the life of the system. They both work on the same field of endeavor.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chun-Cheng Wang whose telephone number is (571)270-5459. The examiner can normally be reached on Monday to Friday w/alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571)272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ling-Siu Choi/
Primary Examiner, Art Unit 1796

/Chun-Cheng Wang/
Examiner, Art Unit 1796

/CCW/